Attorney Docket: 101195-48

REMARKS

Claims 1-13 and 19-23 are under examination. The foregoing amendments are fully supported by the specification and it is believed that no new matter has been added.

Claims 1 and 13 are reproduced below without the amendments for the Examiner's convenience:

Claim 1 (Currently amended)

1. An isolated polynucleotide of SEQ ID NO: 1, or an isolated polynucleotide comprising at least 88% identity with the polynucleotide sequence of SEQ ID NO: 1, the polynucleotide comprising a seed-specific promoter suitable for expressing arbitrary genes in plant seeds.

13. Method for preparing a plant cell comprising an expression cassette according to claim 3 comprising a DNA sequence for seed-specific gene expression into a plant cell, the method comprising the following steps:
    a) providing clone pSBPR15 comprising a DNA sequence according to SEQ ID NO. 1 or a sequence comprising at least 88% identity with the DNA sequence of SEQ ID NO: 1 and possessing promoter activity,
    b) production of the plasmid pSBPOCS making use of the SalI fragment of plasmid pSBPR15 1.9 kb in size,
    c) inserting a polynucleotide encoding a protein into the expression cassette of pSBPOCS,
    d) cloning of the expression cassette containing a DNA sequence for over-expression of foreign genes in plant seeds into binary vectors, and
    e) transfer of the expression cassette containing the foreign gene under the control of the promoter according to SEQ ID NO: 1 into a plant cell.

112, second paragraph Rejections and Claim Objections

It is believed that the amendments to the claims address the rejections made by the Examiner under 35 U.S.C. § 112, second paragraph. (Note: Claim 7 has been amended to depend from claim 4 that provides the required antecedent. With respect to claim 13, the antecedent for the term "the expression cassette" appears in the preamble.)

The occurrence of SBP has been accompanied by the full name - "Sucrose Binding Protein" in claim 11.

Rejection based on Lack of Enablement

(1) Applicants respectfully disagree with Examiner's conclusion that the specification does not enable claims 11-13. Specifically, Applicants respectfully disagree that the specification does not disclose a repeatable process to obtain the exact plasmid. In assessing the propriety of the rejection, attention is focused on the standards for an enabling disclosure as set forth in the MPEP.

The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP § 2164.

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); MPEP § 2164.01(b).

When viewed in light of the PTO guidelines for establishing lack of enablement (see MPEP 2164.01(a) and the *In re Wands*-factors), when considering the totality of the factors, the instant specification is believed to be enabling for the full scope of the claims and would not require undue

experimentation by one of ordinary skill in the art. Specifically, the plasmids in question, pSBPOCS and pPTVBPRGUS and the clones VfSBP20 and pSBPR15 are isolated by the methods sufficiently described in the specification so as to allow persons in the art to practice the invention.

On pages 6-8 the materials and methods disclose, *inter alia*, the following:

- How clone VfSBP20 was isolated and verified (see also Literature reference 15 cited on page 11 of the specification by Grimes et al., "A 62-kD Sucrose Binding Protein Is Expressed and Localized in Tissues Actively Engaged in Sucrose Transport", *The Plant Cell*, vol. 4, pages 1561-1574, (Dec. 1992) - submitted in previous IDS and marked as considered by the Examiner.
- How the clones of SBPR7 and SBPR15 were obtained by PCR, including primer sequences and the commercial kit employed.
- The names of the plasmid, pUC18 used for cloning and sequencing clones SBPR7 and SBPR15.
- The commercial cloning vector and method used for preparing pPTVSBPRGUS is disclosed on page 8, paragraph 3(b).
- The commercial vector and method for preparing pSBPOCS is described on page 9.

All of the procedures would clearly be repeatable by persons of ordinary skill in the art. The commercial vectors and their sequences are known in the art and easily obtainable, and their sequences have been recorded in the literature and commercial literature. The disclosed commercially available PCR and cloning kits have instructions included. Therefore, it is respectfully suggested that the source of materials and the methods of obtaining all disclosed cloned DNAs have

been elucidated in detail. Persons of ordinary skill in the art would have no problem preparing the DNAs and their methods of use to the extent required by the claims.

It is respectfully brought to Examiner's attention that MPEP § 2164.04 explicitly states that "[i]n order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." (*citing* In re Wright, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

In view of the foregoing detailed explanation of the disclosed methodology, it is respectfully suggested that Examiner has not provided adequate rationale to support an enablement rejection of the claimed subject matter. Should Examiner feel it appropriate to maintain the rejection, it is requested she provide a detailed explanation as to why she believes the specification is non-enabling so that Applicants may address the rejection with specificity.

Applicants respectfully suggest that this rejection may be rescinded.

(2) Examiner has also rejected claims 1-10, 19 and 23 for lack of enablement. The thrust of the rejection is that SEQ ID NO: 1 discloses a sequence comprising a seed-tissue specific promoter of 1783 bp. Examiner points out that the largest promoter fragment disclosed and described in the specification is only 1750 bp. Thus, in her view, claims reciting the promoter of SEQ ID NO: 1 are not enabled to full scope of the claims.

Applicants respectfully disagree, although Examiner's conclusion based on the number of base pairs in SEQ ID NO: 1 may be understandable. Referring back to page 7, line 23, a reference is made to the 1539 bp and 1750 bp clones being "on the 5' side of the ATG of the SBP gene...." In accordance with this explanation, if one examines SEQ ID NO: 1, it can be seen that base pairs 1751-3 form an ATG translation initiation codon, i.e., the ATG of the SBP coding sequence. Therefore, the promoter ends at base pair 1750, which is what is disclosed as the length of the larger promoter clone.

Therefore, Applicants respectively suggest that this rejection may also be rescinded.

Rejection based on non-statutory subject matter

The claims (specifically claim 1) have been amended to indicate that the polynucleotide is "isolated" as suggested by the Examiner.

Closing

It is believed that the claims are in condition for allowance. However, should any issue of a minor nature remain, please contact the undersigned to discuss the possibility of an Examiner's Amendment to place the application in condition for allowance.

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CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

Respectfully Submitted,

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Certificate of Transmission

I hereby certify that this correspondence is being transmitted by facsimile to: Hon. Commissioner of Patents at (703) 872-9306 on October 29, 2004
(Date)

AGATA GLINSKA
Typed or printed name of person signing this certificate

Signature Agata Glinska